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| 10/648,158      | 08/25/2003  | Kenneth MC Cheung    | VO690.0008/P008     | 3550             |

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EXAMINER

SHAFFER, RICHARD R

ART UNIT

PAPER NUMBER

3733

MAIL DATE

DELIVERY MODE

06/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/648,158

**Applicant(s)**

CHEUNG ET AL.

**Examiner**

Richard Shaffer

**Art Unit**

3733

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 13 March 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-22, 28, 29 and 32-46 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20-22, 28, 29 and 32-46 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 20-22, 28, 29, 32-43 and 46 rejected under 35 U.S.C. 102(b) as being anticipated by Cool et al (European Patent Application 0 470 660 A1).

Cool et al disclose a method for correcting spinal deformities comprising: providing a correction force with a Ti-Ni (1:1 ratio so it is Nitinol) alloy rod (**Column 4, Lines 54-55**) having various cross-sections (i.e. square, rectangular) and various transition temperatures which can adjust the force applied; a force is present operatively by a nearly constant (and controlled by body temp) corrective force which is activated by the body's own heat (**Column 1, Line 1 through Column 2, Line 26**) during the procedure. The rod is pre-formed to match the spinal rod (**Column 3, Lines 27-59**) and deformed to conform to the spinal deformity (**Column 3, Lines 20-26**) in order to be fixed by anchors (**6**), which act to limit the correction device from rotational movement. Again, in regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited.

Claims 20-22, 28, 29, and 32-46 are rejected under 35 U.S.C. 102(e) as being anticipated by Drewry et al (US Patent 6,783,527).

Drewry et al disclose a method for correcting spinal deformities comprising: providing a constant (inherent and controlled by body temp) correction force through the use of tethers (80) made of superelastic Nitinol (**Column 3, Lines 60-65**) which generates the correction force at body temperature; the forces activated during surgery and are adjusted/set by tensioning the tethers (80) by the surgeon. The tethers (80) are anchored by elements (30 and 50) that are formed of Nitinol (**Column 4, Line 66 through Column 5, Line 6**) which limit rotational movement of the tether. The overall device can be placed anteriorly or posteriorly (**Column 3, Lines 48-55**). The device is deformed to conform to the spinal deformities (inherent due to it being tensioned and anchored to the vertebrae).

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 20-22, 28, 29, 32-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sanders et al (US Patent 5,290,289) in view of Cool et al.

Sanders et al disclose a method for correcting spinal deformities comprising: providing a nearly constant (but adjustable) correction force with a Nitinol (a material

with superelastic/pseudoelastic and shape memory properties) rod (**Column 5, Lines 50-65**). The rod is first pre-contoured to assume normal kyphosis and lordosis (**Column 5, Lines 50-55**) and then deformed to conform to the spinal deformities. The rod is capable of having the force adjusted by remotely heating the rod with a radio frequency induction heater (**Column 7, Lines 55-60**). The heating allows for individual adjustment of the rod sections for corrective force. In regard to claims 28 and 29, anterior and posterior can relate to any direction as broadly recited, and when considering **Figure 2**, it is clear the rod applies force to a side of the vertebra. Nitinol anchor members (bone clamps and blockers; **Column 3, Line 5 through Column 4, Line 11**) are utilized to limit the rod from rotational movement.

Sanders et al disclose all of the claimed limitations except for the correction force being generated at body temperature, but did mention that prior devices loaded the spine at once instead of constant incremental steps. Cool et al teach (**Column 1, Line 1 through Column 2, Line 26**) a similar device that employs using Nitinol to be active at body temperature. It would have been obvious to one having ordinary skill in the art at the time of invention to provide for a rod designed to provide a correction force at body temperature instead of utilizing an external heating as a matter of substitution with predictable results.

Claims 44 and 45 rejected under 35 U.S.C. 103(a) as being unpatentable over Cool et al in view of Sanders et al and Drewry et al. Cool et al disclose all of the claimed limitations except for anchor elements made of Nitinol. Sanders et al (**Column 3, Line 5 through Column 4, Line 11**) and Drewry et al (**Column 4, Line 66 through Column 5,**

**Line 6)** both teach using anchor elements made of Nitinol in order to quickly and firmly attach the rod/tether to bone. It would have been obvious to one having ordinary skill in the art at the time of invention to make the anchor elements of Cool et al out of Nitinol to allow for quick and firm attachment to the rod.

### ***Response to Arguments***

Applicant's arguments filed March 13<sup>th</sup>, 2008 have been fully considered but they are not persuasive. Applicant asserts that the newly added limitations of austenite phase and superelastic material are not disclosed in the prior art. While it was the case in the previous 35 U.S.C. 102(b) rejection as anticipated by Sanders et al, it is incorrect in relation to the 35 U.S.C. 102(b) rejection over Cool et al and the 35 U.S.C. 102(e) rejection over Drewry et al, and the 35 U.S.C. 103(a) rejection over the combination of Sanders et al and Cool et al. As evidenced by Siess et al (US Patent 7,027,875), Column 2, Lines 1-10 clearly state that the device made of a shape memory Nitinol is heated to body heat to achieve superelasticity. Therefore, any Nitinol activated by body temperature is in the superelastic state. Sanders et al before modification requires a heat above body heat, and therefore would generate the forces under the transition temperature and therefore utilize shape memory affect/normal elastic effects. While the other references all are activated at body heat and remain at body heat during treatment and therefore utilize the superelastic state of Nitinol.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard Shaffer whose telephone number is (571)272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Richard Shaffer/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733